

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

GREGORY SIEBER,

Plaintiff,

v.

JOHNSON & JOHNSON,

JOHNSON & JOHNSON CONSUMER,
INC.,

ETHICON, INC.,

ETHICON ENDO-SURGERY, INC.,

ETHICON ENDO-SURGERY, LLC,

ETHICON US, LLC

Defendants,

Civ. File No.

PLAINTIFF’S COMPLAINT

DEMAND FOR JURY TRIAL

TO: ABOVE-NAMED DEFENDANTS AND THEIR ATTORNEYS:

Plaintiff, Gregory Sieber, by and through Plaintiff’s undersigned attorneys, brings this Complaint against Defendants for personal injuries suffered as a result of Defendants’ defective and unreasonably dangerous product, the surgical stapler used in Plaintiff’s February 8, 2019 surgical procedure, and alleges as follows:

I. PARTIES

1. At all times material, Plaintiff has been domiciled in the City of Lakeland, the County of Washington, and the State of Minnesota.

2. Defendant Johnson & Johnson (hereinafter “J&J”) is the parent corporation of the Johnson & Johnson family of companies, organized and existing under the laws of the State of New Jersey. J&J’s principal place of business is at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. At all times relevant to this action, J&J has conducted substantial business in Minnesota and regularly caused its products to be sold in Minnesota, including the product at issue in this case.

3. Defendant Johnson & Johnson Consumer, Inc. (hereinafter “J&J Consumer”) is a subsidiary of J&J.¹ J&J Consumer is a corporation organized and existing under the laws of the State of New Jersey. J&J Consumer’s principal place of business is at 199 Grandview Road, Skillman, NJ 08558. At all times relevant to this action, J&J Consumer has conducted substantial business in Minnesota and regularly caused its products to be sold in Minnesota, including the product at issue in this case.

4. Defendant Ethicon, Inc. (hereinafter “Ethicon”) is a subsidiary of J&J.² Ethicon is a corporation organized and existing under the laws of the State of New Jersey. Ethicon’s principal place of business is at Highway 22, Somerville, New Jersey, 08876. At all times relevant to this action, Ethicon has conducted substantial business in Minnesota and

¹ *Subsidiaries*, SEC, <https://www.sec.gov/Archives/edgar/data/200406/000020040619000009/ex21-subsidiariesxform10xk.htm> (last accessed May 25, 2021).

² *Id.*

regularly caused its products to be sold in Minnesota, including the product at issue in this case.

5. Defendant Ethicon Endo-Surgery, Inc. (hereinafter “EES-Inc.”) is a subsidiary of J&J.³ EES-Inc. is a corporation organized and existing under the laws of the State of Ohio. EES-Inc.’s principal place of business is at 4545 Creek Road, Blue Ash, Ohio, 45242. At all times relevant to this action, EES-Inc. has conducted substantial business in Minnesota and regularly caused its products to be sold in Minnesota, including the product at issue in this case.

6. Defendant Ethicon Endo-Surgery, LLC (hereinafter “EES-LLC”) is a subsidiary of J&J. EES-LLC is a Delaware limited liability company with its principal place of business in Puerto Rico. EES-LLC’s Certificate of Authorization to do Business as a Foreign Corporation filed with the Puerto Rico Registry of Corporations and Entities lists its designated office address in Puerto Rico as 475 Street C Los Frailes Industrial Park, Suite 401, Guaynabo, Puerto Rico, 00969 with its Corporate Domicile as 1209 Orange Street, Wilmington, Delaware, 19801. EES-LLC is a single-member LLC owned wholly by EES-Inc. In the alternative, EES-LLC’s sole member is one of the Johnson & Johnson family of companies or is a combination of multiple members of the Johnson & Johnson family. No member of EES-LLC is a citizen of Minnesota, domiciled in Minnesota, or headquartered in Minnesota. At all times relevant to this action, EES-LLC has conducted

³ *Id.*

substantial business in Minnesota and regularly caused its products to be sold in Minnesota, including the product at issue in this case.

7. Defendant Ethicon US, LLC (hereinafter “Ethicon US”) is a subsidiary of J&J.⁴ Ethicon US is a Texas limited liability company with its principal place of business at 1125 Bear Tavern Road, Titusville, New Jersey, 08560. Ethicon US is a single-member LLC owned wholly by EES-Inc. In the alternative, Ethicon US’s sole member is one of the Johnson & Johnson family of companies or is a combination of multiple members of the Johnson & Johnson family. No member of Ethicon US is a citizen of Minnesota, domiciled in Minnesota, or headquartered in Minnesota. At all times relevant to this action, Ethicon US has conducted substantial business in Minnesota and regularly caused its products to be sold in Minnesota, including the product at issue in this case.

8. At all relevant times, Defendants Johnson & Johnson, Johnson & Johnson Consumer, Inc., Ethicon, Inc., Ethicon Endo-Surgery, Inc., Ethicon Endo-Surgery, LLC, and Ethicon US, LLC (hereinafter collectively “Defendants”) were engaged in the business of, or were successors in interest to entities engaged in the business of, researching, designing, testing, manufacturing, producing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling, surgical staplers including the surgical stapler at issue in this case. This device was for use by the Plaintiff and Plaintiff’s physicians. As such, Defendants are individually, jointly, and severally liable to Plaintiff for damages suffered by Plaintiff arising from

⁴ *Id.*

Defendants' design, manufacturing, marketing, labeling, distribution, sale, and placement of the defective surgical stapler at issue in this suit. All acts were effectuated directly or indirectly through Defendants' respective agents, servants, employees, and/or owners, acting within the course and scope of their representative agencies, services, employments, and/or ownership.

II. JURISDICTION AND VENUE

9. This Court has jurisdiction pursuant to 28 U.S.C. §1332, as complete diversity exists between Plaintiff and Defendants, and the amount in controversy exceeds \$75,000.

10. Defendants are subject to in personam jurisdiction in this court, and venue is proper within this district pursuant to 28 U.S.C. § 1391, as a substantial number of the events, actions, or omissions giving rise to the Plaintiff's claims occurred in this district. At all times relevant to this matter, Defendants conducted substantial business in this district. Defendants did (and do) business within the state of Minnesota and have had substantial, continuous, and systematic contacts with the state of Minnesota, have consented to jurisdiction in the state of Minnesota, and/or committed a tort in whole or in part in the state of Minnesota, against Plaintiff herein, as more fully set forth below.

III. FACTUAL ALLEGATIONS

11. Defendants directly or through their agents, apparent agents, servants, or employees, do business in the State of Minnesota, including, but not limited to, work related to designing, manufacturing, marketing, selling, and distributing surgical staplers, including the surgical stapler at issue in this case.

General Background Regarding Surgical Stapler Products

12. Since the early 1900s, surgical staplers have been used in a number of medical operations and procedures.⁵

13. Typically, a stapler is comprised “of the stapler body, a staple cartridge/reload with lines of staplers, an anvil, and a firing mechanism. The surgeon loads a staple cartridge into the stapler (unless they are using a preloaded device) before placing the tissue to be connected between the stapler jaws (comprised of the cartridge and anvil). They then activate the firing mechanism to shoot a staple into place.”⁶

14. Innovations in the manufacturing of surgical staplers have led to the creation of staplers for specific procedures. One of these is the circular stapler, which is used in colorectal, gastric, and thoracic surgeries.

15. Over the years, surgical staplers have been used to remove a part of an organ (otherwise known as a “resection”), to cut through tissue and organs (“transection”), and to create connections between structures in the body (“anastomoses”).⁷

16. The advantages of using surgical staples and staplers include: “Quick placement; Minimal tissue reaction; Low risk of infection; [and] Strong wound closure.”⁸

17. Despite their many uses and advantages, surgical staplers also have a long history of malfunctions. For example, by 2004 studies had shown that 112 deaths, 2,180 injuries,

⁵ See Sophie Childs, *Surgical Staples: Everything Healthcare Professionals Need to Know*, CIA (Apr. 18, 2017) <https://www.ciamedical.com/insights/everything-healthcare-professionals-need-to-know-about-surgical-staples/>.

⁶ *Id.*

⁷ *Surgical Staplers and Staples*, FDA (June 25, 2019), <https://fda.gov/medical-devices/general-hospital-devices-and-supplies/surgical-staplers-and-staples>

⁸ *Id.*

and 22,804 adverse events (“AEs”) were reported to the FDA connected to surgical stapler use.⁹

18. In fact, one survey found that the incidence rate of stapler malfunction is so high that “86% of laparoscopic surgeons either had personal experience with or knew of surgeons who experienced stapler malfunction.”¹⁰

19. Other studies found that between 8,000 and 9,000 AEs related to surgical staplers occur each year, with 90% of these AEs resulting from a malfunction with the device.¹¹

20. Further, the possible consequences of a malfunction are often very serious. As the FDA explained, “[i]n a retrospective study of 349 colorectal resections using a circular stapler, surgeries with surgical stapler malfunctions were found to have higher incidences of unplanned proximal diversions, ileus, gastrointestinal bleeding, and blood transfusions.” Likewise, “[a]nastomotic leaks from surgical stapler malfunctions have also been associated with an increased risk of cancer recurrence.”¹²

21. Even if the malfunction does not cause a potentially fatal injury for the patient, such “complications frequently require additional diagnostic studies, invasive procedures and in the need for reoperation resulting in prolonged hospitalization and additional skilled nursing care.”¹³

⁹ See S. Lori Brown, *Surgical stapler-associated fatalities and adverse events reported to the Food and drug Administration*, JACS (May 2004), available at [https://www.journalacs.org/article/S1072-7515\(04\)00754-9/abstract](https://www.journalacs.org/article/S1072-7515(04)00754-9/abstract).

¹⁰ Samwel Okoth Makanyengo and Dhan Thiruchelvam, *Literature Review on the Incidence of Primary Stapler Malfunction*, 27 SURG. INNOV., 229-34 (Apr. 2020).

¹¹ *Everything Healthcare Professionals Need to Know*, *supra* note 15.

¹² *FDA Executive Summary*, FDA (May 30, 2019), 11, <https://www.fda.gov/medical/126211/download>.

¹³ *Id.* at 9.

22. As a result of these complications and the ubiquitous malfunctions that have plagued surgical staplers for years, the FDA performed a review of the studies that have been conducted to investigate these issues.¹⁴

23. After examining these studies, the FDA concluded the most commonly reported malfunctions associated with surgical staplers include malformed staples, missing staples, stapler jamming, and misfires.¹⁵

24. By 2013, Defendants and the medical device industry in general knew or should have known that malfunctioning surgical staplers such as the product used in Plaintiff's February 8, 2019 surgery presented serious risk of injury during surgery and that the true risk of injury was unknown and unexamined. Despite this obvious problem, these Defendants took no steps to measure the true risks of these devices or warn surgeons and their patients of the true risk.

25. Defendants at all relevant times were or should have been aware of the dangers a defective surgical stapler posed for patients and should have and were expected to maintain effective procedures to properly manufacture their surgical staplers and appropriately respond when their surgical staplers were found to be defective. Unfortunately, this is not the case even though Defendants knew or should have known that their surgical stapler products, including the product used in Plaintiff's February 8, 2019 surgery, were defective and unreasonably dangerous.

¹⁴ *Id.* at 10.

¹⁵ *Id.* at 10-11.

Information Regarding Defendants' Surgical Stapler Products

26. The Ethicon Defendants asserted in the “surgical stapling” portion of their product catalog:

Reliable tissue repair is a critical factor for all surgery. That’s why Ethicon has worked with surgeons worldwide to develop and refine our surgical staplers and cutters. Our surgical stapling portfolio addresses the issues of tissue thickness, staple line security, and tissue tension to provide you solutions that are designed to enhance control and patient safety.¹⁶

27. As explained below, the surgical stapler sold for use in Plaintiff’s surgery did not provide “[r]eliable tissue repair” or “staple line security” nor did it “enhance ... patient safety.”

28. Defendants continue to promote their circular staplers as superior due to “controlled compression for a strong anastomosis” and less tissue damage.¹⁷

29. As explained below, the surgical stapler sold for use in Plaintiff’s surgery did not create a “strong anastomosis” nor did it minimize tissue damage.

30. According to the FDA’s Manufacturer and User Facility Database (MAUDE), from January 5, 2009 to July 3, 2016, the Defendants received more than 300 reports of injury and malfunction related to their curved intraluminal staplers. These included complaints that the staples had not formed completely.

¹⁶ <https://pdf.medicalexpo.com/pdf/ethicon/2016-ethicon-product-catalog/74984-154353-27.html> (last accessed May 25, 2021).

¹⁷ <https://www.jnjmedicaldevices.com/sites/default/files/2021-02/ETHICON-Circular-Stapler-Product-Fact-Sheet-157049-201217.pdf> (last accessed May 25, 2021).

31. The number of AEs is likely significantly underreported, because it is widely recognized in the medical device industry and by the FDA that the MAUDE database only contains a small fraction of the actual AEs reported to the FDA.

32. In addition, there is no requirement that AEs are reported by physicians. This results in further underreporting.

The Recall of Defendants' Surgical Stapler Products

33. On April 11, 2019, Defendants issued a Class I recall (the most serious type) of Ethicon Curved Intraluminal Staplers that were manufactured between March 6, 2018 and March 6, 2019 and distributed between March 15, 2018 and March 8, 2019. They recalled 92,496 staplers. Upon information and belief, the surgical stapler used in Plaintiff's February 8, 2019 surgery was amongst those recalled by Defendants.

34. Pursuant to investigation of complaints and returned products, Defendants confirmed that uncut washers in the stapler and malformed staples occurred with their intraluminal circular staplers due to insufficient firing thereby compromising staple line integrity. The recall further stated that the failure to cut the washer suggests complete 360-degree staple line failure which could lead to potential risks to patients including death, sepsis, bleeding, the need for a permanent ostomy bag, life-long nutritional and digestive issues, anastomotic leaks, additional surgeries, the need for additional anastomoses, the need for antibiotics, and the need for additional imaging studies. The recall also stated that an investigation conducted by Defendants of the manufacturing process of the Ethicon Endo-Surgery Intraluminal Staplers detected a shift in a process, which occurred in March of 2018 through March 8, 2019, at which time the line was shut down.

35. On May 15, 2019, the FDA issued a Class I recall for Defendants' intraluminal staplers which were designed and manufactured for use in gastrointestinal surgeries. The recall was issued, because the stapler may have an insufficient firing stroke to break the washer and completely form staples. The recall also referenced the shift in process discussed in the preceding paragraph. This recall notice is still active.

Allegations Specific to Plaintiff

36. On February 8, 2019, Plaintiff underwent esophagogastrosomy, laparotomy with total gastrectomy, distal esophagectomy and intrathoracic Roux-en-Y esophagojejunostomy, abdominal lymphadenectomy, transhiatal ligation of thoracic duct, feeding jejunostomy, left pharyngostomy tube placement, right tube thoracostomy, and left tube thoracostomy. This procedure was necessitated by Plaintiff's development of a malignant neoplasm at the gastroesophageal junction and was performed by Dr. Rafael Andrade. In the operative report, Dr. Andrade noted: "We transected the esophagus gradually at 5 cm above the upper limit of the tumor and placed a 2-0 prolene purse-string as we transected it. We placed a 25 anvil into the lumen and tightened the purse-string. Once we verified that the jejunum was properly oriented and appeared well vascularized, we amputated the very end and placed the EEA stapler into it. We performed the anastomosis transhiatally without difficulty and had 2 complete mucosal doughnuts."

37. Upon information and belief, the surgical stapler used in Plaintiff's February 8, 2019 procedure was designed, manufactured, marketed, sold, and distributed by Defendants.

38. Within days, Plaintiff became critically ill due to an esophagojejunostomy anastomotic leak which occurred due to the failure of the surgical stapler used in the February 8, 2019 procedure.

39. On February 12, 2019, a CT of Plaintiff's chest/abdomen done without contrast showed small to moderate bilateral hydropneumothoraces with left greater than right, bibasilar chest tubes in place, large dependent consolidative opacity with volume loss in the left lower lung, stable postsurgical changes of distal esophagectomy, gastrectomy, and intrathoracic esophagojejunostomy, mild soft tissue thickening, and air foci along the suture line of esophagojejunostomy. Superimposed infection was a concern, and leakage with possible communication with the left hemithorax could not be ruled out. Further evaluation with a dedicated esophagram was considered.

40. On February 15, 2019, Plaintiff underwent a flexible bronchoscopy, upper endoscopy, and pharyngostomy tube placement. Per the operative report, the anastomotic leak was immediately visualized at the cervical jejunostomy and led to a cavity into the left chest. A pharyngostomy was performed that drained this cavity, and a pharyngostomy tract was created in the right neck by passing the clamp posterior to the posterior tonsillar pillar to emerge at the right neck. An 18-French Salem sump tube was then tunneled through this to be brought out through Plaintiff's mouth. A pediatric scope was then inserted orally into the defect in the cavity, and a 260 Super Stiff Amplatz was then passed through. The scope was then removed, and the saline sump tube was tunneled over the wire to lie in the cavity with fluoroscopic visualization. This was then secured in place. After this, Plaintiff

was extubated and transferred to the recovery room in stable condition. He was diagnosed with anastomotic leak, status post esophagectomy and esophagojejunostomy.

41. On February 19, 2019, Plaintiff then underwent a flexible bronchoscopy, esophageal flexible esophagojejunostomy, fluoroscopy interpretation of images, repositioning of the right pharyngostomy tube, left thoracotomy with decortication and intercostal muscle flap mobilization, and reinforcement of anastomotic leak. As part of the procedure, a single lung ventilation was performed in Plaintiff's left chest due to a copious amount of secretions. Plaintiff's entire chest cavity was cleaned, and an intercostal nerve pedical was placed between Plaintiff's aorta and the leak so as to prevent the pharyngostomy tube from directly contacting Plaintiff's aorta. After copious irrigation and closure, Plaintiff was then reintubated and a flexible laparoscopy was performed to clear copious secretions.

42. On February 28, 2019, a CT of Plaintiff's chest showed postsurgical changes of a distal esophagectomy and total gastrectomy with new pharyngostomy tube extending through the known defect in the surgical anastomosis of the distal esophagus.

43. On March 12, 2019, Plaintiff then underwent an esophagogastroscope, fluoroscopy with interpretation of images, and flexible bronchoscopy. The operative procedure described that, under fluoroscopic guidance, the pharyngostomy tube in the left chest cavity was pulled back so that both openings of the tube were still within the subpleural pulmonary cavity on the left diaphragm. It was then copiously irrigated, and suction was applied. While applying suction under fluoroscopic guidance, it was evident that the space had collapsed entirely. A flexible bronchoscopy was performed to clear secretions from Plaintiff's left lower lobe.

44. On March 30, 2019, an additional CT of Plaintiff's chest/abdomen evidenced new consolidative opacities in the right lower lobe noted as concerning for infection.

45. On April 2, 2019, Plaintiff underwent a flexible esophagojejunostomy, repositioning of the right pharyngostomy tube and left chest tube, and fluoroscopy with interpretation of images.

46. On April 12, 2019, a CT of Plaintiff's chest/abdomen/pelvis showed stable positioning of the pharyngostomy tube via a defect in the left lateral anastomosis status post distal esophagectomy with Roux-en-Y esophagojejunostomy.

47. On April 15, 2019, Plaintiff underwent a right pharyngostomy tube revision and esophagogastroduodenoscopy during which his abscess cavity was found to be completely collapsed.

48. On April 22, 2019, Plaintiff presented to the emergency department for removal of his pharyngostomy tube due to a wound infection around the tube.

49. On May 8, 2019, a CT of Plaintiff's chest/abdomen/pelvis showed postoperative changes and noted a small left pleural effusion with a loculated component and associated pleural thickening and enhancement slightly increased from the prior study. Also noted was an elongated rim-enhancing fluid collection along the track of the previously seen left chest tube likely representing an inflammatory or infectious process.

50. On June 1, 2019, Plaintiff developed tender erythema along the posterior left chest wall which subsequently developed into a boil that spontaneously opened on June 2, 2019 and drained purulent fluid for multiple days.

51. On June 5, 2019, a CT of Plaintiff's chest showed osteomyelitis of the left eighth rib with a surrounding abscess and a suspected fistulous tract to the surface of the skin along the anterolateral left chest wall. There was air within the left eighth rib, highly concerning for gas-forming bacteria versus early necrotizing fasciitis. There was also a suspected pathologic fracture posteriorly and small left empyema. Concerns were noted for chest wall abscess with surrounding cellulitis and lower back rash.

52. On June 6, 2019, Plaintiff underwent resection of his left 10th rib as well as irrigation and debridement of his chest wall abscess. The operation procedure described an incision being made along the left 10th rib extending posteriorly to the vertebral bodies and anteriorly to the sinuses that were draining. An area of necrotic tissue and an abscess cavity were identified around the left 10th rib. The 10th rib was resected and disarticulated from the transverse process, and it was removed in two pieces. The area was connected to the draining sinuses and opened up at the cavity.

53. The failure of the surgical stapler and staples to properly create an anastomosis during Plaintiff's February 8, 2019 procedure has resulted in a number of complications, including placement of pharyngostomy and chest tubes, reinforcement of the anastomosis via an intercostal muscle flap, multiple procedures to adjust the pharyngostomy and chest tubes, a large chest abscess, rib osteomyelitis and removal, and months of hospitalization. Plaintiff continues to experience severe and debilitating pain as a result of the stapler failure.

54. As a result of the failure of Defendants' surgical stapler, Plaintiff has sustained significant past and future hospital and medical expenses, pain and suffering, disability, restrictions, disfigurement, and permanent damage.

IV. CAUSES OF ACTION

COUNT I

Defective Design – Negligence and Strict Products Liability

55. Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

56. A Defendant who designs a medical device or instrument such as a surgical stapler, and who sells or otherwise distributes a defective device, is subject to liability for harm to persons caused by the design defect. A reasonably prudent manufacturer must design its products so as to avoid any unreasonable risk of harm to anyone who is likely to be exposed to the harm when the product is put to its intended use or to any use that is unintended but is reasonably foreseeable. A medical device is defective if, at the time of sale, the device is designed in such a way that it poses harm and risk of injury when used by the intended consumer in the manner the manufacturer has directed and designed.

57. A reasonably prudent manufacturer of surgical staplers would know that a dangerous risk of surgery such as Plaintiff's February 8, 2019 surgery is the risk of anastomotic leak. In other words, a reasonable and prudent manufacturer is or should be aware of the risk that, if the product is defective, the anastomosis the stapler is intended to create could fail. A reasonably prudent manufacturer of such products would also know

that such anastomotic failure could cause death and/or serious injury requiring hospitalization, additional surgeries, and significant medical care.

58. Plaintiff was harmed by Defendants' defective surgical staplers, which were designed, manufactured, distributed, and sold by Defendants. Defendants' surgical staplers contained a design defect that made the products unreasonably dangerous for their intended use. Plaintiff and Plaintiff's physician could not have anticipated the danger the defective surgical staplers created. Specifically, there was a design defect that would result in an anastomotic leak despite proper utilization by a surgeon. That design defect in the staplers existed when those products left the Defendants' control.

59. As a direct and proximate result of Defendants' defective design of the surgical stapler at issue, Plaintiff has suffered injuries, including, but not limited to, anastomotic leak, abscess, surgical intervention, hospitalization, increased risk of cancer recurrence, and pain. Consequently, Plaintiff has suffered damages and has incurred, and will continue to incur, medical expenses. Plaintiff has suffered, and will continue to suffer, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

COUNT II

Defective Manufacturing – Negligence and Strict Products Liability

60. Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

61. A manufacturer of a medical device or instrument such as a surgical stapler who sells or otherwise distributes a defective device is subject to liability for harm to persons

caused by the defect. A medical device is defective if, at the time of sale, the device departs from its intended design even though all possible care was exercised in the preparation and marketing of the product. Thus, a medical device is defective if, at the time of sale, the device is manufactured in such a way that it poses harm and risk of injury when used by the intended consumer as the manufacturer intended.

62. A reasonably prudent manufacturer of surgical staplers would know that a dangerous risk of surgery such as Plaintiff's February 8, 2019 surgery is the risk of anastomotic leak. In other words, a reasonable and prudent manufacturer is or should be aware of the risk that, if the product is defective, the anastomosis the stapler is intended to create could fail. A reasonably prudent manufacturer of such products would also know that such anastomotic failure could cause death and/or serious injury requiring hospitalization, additional surgeries, and significant medical care.

63. A reasonably prudent manufacturer of surgical staplers would know that, if it failed to exercise reasonable care in the manufacture of its product, as was its duty, that its product could malfunction and/or fail to properly and permanently close a surgically repaired site causing anastomotic leak and other serious, related harm.

64. Defendants' stapler(s) were manufactured in such a way as to deviate from their intended design and render those staplers unreasonably dangerous to the patient. Plaintiff and Plaintiff's physician could not have anticipated the danger the defective surgical staplers created. Specifically, there was a manufacturing defect that would result in an anastomotic leak despite proper utilization by a surgeon. That manufacturing defect in the staplers existed when those products left the Defendants' control.

65. As a direct and proximate result of Defendants' defective manufacture of the surgical stapler at issue, Plaintiff has suffered injuries, including, but not limited to, anastomotic leak, abscess, surgical intervention, hospitalization, increased risk of cancer recurrence, and pain. Consequently, Plaintiff has suffered damages and has incurred, and will continue to incur, medical expenses. Plaintiff has suffered, and will continue to suffer, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

COUNT III
Failure to Warn – Negligence and Strict Products Liability

66. Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

67. A manufacturer must use reasonable care in giving adequate and accurate instructions as to the use of a product as well as a warning as to any dangers reasonably foreseeable in its intended use. The warning must be in a form which could reasonably be expected to catch the attention of, and be understood by, the ordinary user. Thus, a medical device is defective if, at the time of sale, the warnings and instructions provided with the device fail to provide adequate warnings of the dangers inherent in the product's proper use.

68. A reasonably prudent manufacturer of surgical staplers would know that a dangerous risk of surgery such as Plaintiff's February 8, 2019 surgery is the risk of anastomotic leak. In other words, a reasonable and prudent manufacturer is or should be aware of the risk that, if the product is defective, the anastomosis the stapler is intended to

create could fail. A reasonably prudent manufacturer of such products would also know that such anastomotic failure could cause death and/or serious injury requiring hospitalization, additional surgeries, and significant medical care.

69. Defendants knew or should have known that their surgical staplers posed a risk to patients when used as intended, because defects were present in the products that would result in an anastomotic leak despite proper utilization by a surgeon. Despite this knowledge, Defendants failed to adequately warn potential surgeons or patients at the time they discovered, or should have discovered, those defects. Defendants were negligent for not providing sufficient notice or warnings of the risks associated with using the subject surgical staplers, including the risks associated with malfunction. Those inadequate warnings and instructions existed at the time the staplers left Defendants' control.

70. As a direct and proximate result of Defendants' failure to warn, Plaintiff has suffered injuries, including, but not limited to, anastomotic leak, abscess, surgical intervention, hospitalization, increased risk of cancer recurrence, and pain. Consequently, Plaintiff has suffered damages and has incurred, and will continue to incur, medical expenses. Plaintiff has suffered, and will continue to suffer, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

COUNT IV
Breach of Implied Warranty for Fitness for a Particular Purpose

71. Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

72. Defendants had reason to know of healthcare providers' particular purpose for buying their surgical staplers – to use those staplers in surgical procedures such as Plaintiff's February 8, 2019 surgery for the creation of anastomoses.

73. Healthcare providers, including Plaintiff's healthcare providers, in buying Defendants' surgical stapler products relied on Defendants' judgment and skill in designing, manufacturing, and selling surgical staplers when they selected the surgical stapler products to be used in Plaintiff's surgery. Defendants had reason to know of such reliance, yet Defendants' surgical stapler products, including the surgical stapler used during Plaintiff's February 8, 2019 surgery, were not fit for the particular purpose of creation of anastomoses.

74. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered injuries, including, but not limited to, anastomotic leak, abscess, surgical intervention, hospitalization, increased risk of cancer recurrence, and pain. Consequently, Plaintiff has suffered damages and has incurred, and will continue to incur, medical expenses. Plaintiff has suffered, and will continue to suffer, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

COUNT V Negligence

75. Plaintiff hereby incorporates the allegations contained in the preceding paragraphs, as though fully set forth herein.

76. Defendants owed Plaintiff a duty to use reasonable care in the design, manufacture, distribution, and sale of their surgical stapler products to protect people likely to be exposed to unreasonable risk of harm.

77. Defendants breached that duty in failing to use reasonable care and providing defective surgical stapler products for use in Plaintiff's February 8, 2019 surgery.

78. As a direct and proximate result of Defendants' actions and omissions, Plaintiff has suffered injuries, including, but not limited to, anastomotic leak, abscess, surgical intervention, hospitalization, increased risk of cancer recurrence, and pain. Consequently, Plaintiff has suffered damages and has incurred, and will continue to incur, medical expenses. Plaintiff has suffered, and will continue to suffer, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgement against Defendants as follows:

1. For an award of damages sufficient to compensate the Plaintiff for damages in excess of \$75,000.00, including but not limited to past, present, and future economic expenditures, pain and suffering, and damage to quality of life.
2. For all applicable statutory remedies provide by law in Minnesota that assert liability for Defendants' wrongdoings and improper conduct;
3. For prejudgment interest, as permitted by law;
4. For reasonable costs, including attorney's fees as permitted by law; and
5. For all other just and proper relief.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

Respectfully Submitted,

GOLDENBERGLAW, PLLC

Dated: May 28, 2021

/s/ Noah C. Lauricella

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